## REMARKS

**Status of the claims**

Claims 24-32 and 34-38 are pending in the application.

**Rejections under 35 U.S.C.§103**

1) *Nagaoka '615 and Nagaoka '330 (claims 24, 25 and 35-38)* – Claims 24, 25, and 35-38 have been rejected under 35 U.S.C.§103 as being obvious over Nagaoka '615 and Nagaoka '330. The Examiner asserts that Nagaoka '615 teaches at column 1, lines 30-44 that "their *Lentinus edodes* (shitake) mycelium extract is effective as an anti-tumor agent...." Applicants traverse this rejection and withdrawal thereof is respectfully requested.

The Examiner has misinterpreted the reference with the above quoted description of the reference teachings. The section of the references that the Examiner relies upon in Nagaoka '615 refers to the prior art preparation not the preparation of the Nagaoka '615 inventors. Specifically, the Nagaoka '615 is discussing in the cited section, the findings of Oka et al., as reported in the article "Antitumor Activity of Some Plant Polysaccharides (fractionation and antitumor activity of bagasse polysaccharide)", Gann, Vol. 59, 35-42 (1968). There is no disclosure in the Nagaoka '615 and '330 references that an extract of *Lentinus edodes* mycelium has anti-tumor activity.

In the final line of page 6, the Examiner further notes that the "functional cell activity effect" is inherent to the extract of Nagaoka '615. However the Examiner applies an improper legal evaluation of the reference with this statement. If something is "intrinsic" or "inherent" it occurs without any appreciation for that occurrence. However, for a rejection of obviousness there must be some suggestion to one skilled in the art of the necessary modifications to achieve the invention. Such a suggestion impossible if something is only intrinsically present with no appreciation.

Finally, the Examiner further notes at column 6, lines 35-44 that several different enzymes can be used by Nagaoka '615. However, the Examiner is improperly picking and choosing only select portions of Nagaoka '615 without considering the overall teachings of the reference. Nagaoka '615 teaches overall that the mycelial cell walls of mycelia should be enzymatically lysed to make a preparation high in β-glucan because β-glucan has anti-tumor properties. As noted in the response of July 28, 2005 it is believed by those skilled in the art that the anti-tumor effects of β-glucan are through humoral immunity. This is completely different from the mechanism of the instant invention, which is, as recited in the claims, is through γδ T cell activity. As such, the instant invention is in no way suggested by Nagaoka '615 or Nagaoka '330 and withdrawal of the rejection is respectfully requested.

2) *Nagaoka JP '816 (Claims 26-29 and 38)* – Claims 26-29 and 38 remain rejected under 35 U.S.C.§103 as being obvious over JP '816. In response to Applicant's arguments of July 28, 2005, the Examiner notes that the English abstract of JP '816 does teach the antibacterial activity of the *Lentinus edodes* extract.

Claim 26 recites a method of treating a bacterial or viral infection, by administering to a patient an extract of *Lentinus edodes* mycelium, which enhances γδ T cell activity. Thus, the invention of claim 26, as recited in the claim, is an indirect antibacterial activity that functions through the enhancement of on particular part of the immune system, i.e. γδ T cells.

As noted by the Examiner, JP '816 does disclose that an extract of *Lentinus edodes* has an "antibacterial" activity. However, there is a key difference between the activity reported in JP '816 and that encompassed by claim 26. Attached hereto is partial translation of Example 1 of JP '816. As seen from the translation of the reference example, JP '816 reports the antibacterial activity of *Lentinus edodes* mycelium, as determined using a "MIC" (minimum inhibitory

concentration) method. The MIC method measures the minimum concentration of a given product by the direct inhibition of bacterial growth by the product. See for example, paragraphs [0060]-[0061] of US 20030077239 and paragraphs [0079]-[0061] of US 20060100277.

As seen from the indicated sections of US '239 and US '277, the MIC method measures the direct inhibition of bacterial growth by a product. The MIC method cannot determine whether there is any indirect antibacterial activity of a product through, for example, the enhancement of immune activity by the product. Claim 26 explicitly recites that the mechanism of antibacterial activity of the invention is through enhancement of γδ T cell activity. As such, the disclosure in JP '816 is not relevant to the instant invention and withdrawal of the rejection is respectfully requested.

In view of the above Remarks, Applicant believes the pending application is in condition for allowance.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

If the Examiner has any questions concerning this application, the Examiner is requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of (703) 205-8000.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

By _____

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